UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

UNITED STATES OF AMERICA,)
Plaintiff,)
v. ·) CIVIL ACTION NO.
LAO TRADING COMPANY AND PENG BANDITH,)))
Defendants.)

COMPLAINT FOR PERMANENT INJUNCTION

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

- 1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), to permanently enjoin the defendants, Lao Trading Company and its owner, Peng Bandith (collectively, "Defendants"), from causing food to become adulterated, within the meaning of 21 U.S.C. § 342(a)(4), while such food is held for sale after shipment in interstate commerce, in violation of 21 U.S.C. § 331(k).
- 2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).
 - 3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants

4. Defendant Lao Trading Company does business at 449 Atlas Drive, Nashville, Tennessee 37211-3307 ("Defendants' facility"), within the jurisdiction of this Court. Lao Trading Company operates a food storage warehouse at which it receives and holds food for sale after shipment in interstate commerce.

5. Defendant Peng Bandith is the owner of Lao Trading Company. He performs his duties at Defendants' facility, where he is present on a daily basis and is responsible for all activities at the firm including warehouse operations, building and equipment maintenance, supervision of employees, and the maintenance of proper sanitary conditions.

Defendants' Operations

6. Defendants have been and are currently engaged at Defendants' facility in receipt, storage, and distribution of articles of food, within the meaning of 21 U.S.C. § 321(f), such as vermicelli noodles and rice. Further, Defendants have been and are currently engaged in receiving these articles of food from other states, including, but not limited to, California and distributing those articles within the state of Tennessee.

Defendants' Violative Conduct

- 7. Defendants violate 21 U.S.C. § 331(k) by causing food held for sale after shipment in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that such food is prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may been rendered injurious to health.
- 8. FDA inspected Defendants' facility in June 2010. At that visit, FDA investigators found overwhelming evidence of rodent, insect, and bird infestations throughout the facility. The litany of violative conditions the investigators observed included:
- A. Defendants' failure to maintain fixtures and physical facilities to prevent food from becoming adulterated, evidenced by a substantial gap along the entire bottom of the loading dock door, holes in screens of doors within the facility, holes in the ceiling of rooms and a collapsing ceiling in one room, gaps between the wall and baseboard of two rooms, and numerous holes in the walls of several rooms;
- B. Defendants' failure to keep the loading dock door closed during three days of inspection;

- C. Defendants' failure to store and transport finished food under conditions that would protect against physical, chemical, and microbial contamination;
- D. Defendants' failure to leave open sufficient space in their warehouse to maintain sanitary operations;
- E. Defendants' failure to remove litter and waste and cut weeds or grass within the immediate vicinity of the building, rendering the area attractive to rodents and other pests; and
- F. Defendants' failure to provide adequate lighting in areas where food is examined, stored, or processed.
- 9. In addition to these violative conditions, Defendants fail to maintain sanitation control records that document monitoring and corrections of sanitation deficiencies for the condition and cleanliness of food contact surfaces, prevention of cross contamination from insanitary objects, maintenance of hand washing, hand sanitizing, and toilet facilities, protection of food, food packaging material, and food contact surfaces from adulteration, proper labeling, storage and use of toxic chemicals, and exclusion of pests.
- 10. In response to the deplorable conditions FDA found at Defendants' facility during the June 2010 inspection, on June 14, 2010, the state of Tennessee suspended Defendants' business license and oversaw the destruction of adulterated articles of food stored within the facility and a clean-up of the rodent infestation. The state re-issued Defendants' business license on or about June 25, 2010, after the clean-up was completed. Defendants' however, have not altered their policies or procedures to ensure that sanitary conditions at the facility will be maintained.

Defendants' Past Violative Conduct

- 11. FDA previously inspected Defendants' facility in July 2001. At that inspection, FDA investigators found evidence of past rodent activity at the facility, although they did not find evidence of an active infestation.
- 12. In April 2003, FDA re-inspected Defendants' facility. FDA investigators found numerous problems with the firm's sanitation practices, including inadequate protection against pests; overcrowding of products; dented cans and broken bags of rice in stock; poor facility maintenance; and, no hazard analysis and critical control points ("HACCP") plan, see 21 C.F.R. § 123.6, or written sanitation monitoring procedures in place for the distribution of frozen seafood products. At the conclusion of the inspection, the investigators issued a Form FDA 483, Inspectional Observations, to Bandith, identifying the violative conditions. The investigators discussed the violations with Bandith and he agreed to make some of the necessary corrections immediately, although he requested more time to analyze the seafood HACCP requirements and make corrections.
- 13. In January and February 2005, FDA again inspected Defendants' facility. In spite of promised corrections, Defendants showed little, if any, progress in correcting the violative conditions identified during the previous inspection. At that time, FDA investigators found Defendants had a continuing and active pest problem throughout their facility resulting in wide-spread adulteration of articles of food. Subsequent laboratory analyses confirmed rodent activity in and on bags of beans and rice held at the facility. Furthermore, investigators observed structural defects and damage permitting rodent access throughout the warehouse. Deviations from the seafood HACCP requirements also continued.
- A. In light of the active rodent infestation at Defendants' facility, United States Marshals, at the direction of FDA, seized all food in rodent susceptible containers in the facility, pursuant to a Warrant of Arrest in Rem filed on March 2, 2005, in this Court.

Defendants filed a claim for the seized articles, and subsequently agreed to a Consent Decree of Condemnation and Injunction, signed by Bandith, in which they agreed, among other things, to recondition the seized articles to FDA's satisfaction or destroy them; thoroughly clean, renovate, and render their facility suitable for use in handling food; eliminate from the facility all rodents and other pests and make repairs to preclude their future entry into the facility; establish a written sanitation control program to ensure that their facility was continuously maintained in a sanitary condition; and assign responsibility for the operation of such program to a person competent to maintain the facility and the equipment contained therein in a sanitary condition. The Consent Decree was signed and entered by United States District Judge Robert Echols on May 25, 2005.

- B. Following reconditioning and destruction of the seized articles, FDA reinspected Defendants' facility in November 2005 to assess the adequacy of structural repairs made to the facility and to determine if the warehouse was suitable for the storage of food products in a manner to prevent adulteration, as required by the Consent Decree. The FDA investigators found that all doors appeared to be sealed to prevent rodent entry; Defendants had repaired existing holes in walls and sealed the walls at the wall/floor juncture; Defendants had moved all storage racks away from the walls to allow cleaning and monitoring of rodent or insect activity; finally, Defendants had installed a new roll-up garage door at the dock entrance. The Consent Decree was subsequently vacated.
- 14. In August 2006, FDA again inspected Defendants' facility. At that inspection, less then a year after entry of the initial Consent Decree, FDA found general storage conditions within Defendants' facility continued to comply with applicable regulations. FDA investigators did note, however, some damaged product containers and open food product that was left open to contamination. In addition, the investigators noted that Defendants were not monitoring the temperature of the freezer used to store seafood, and issued a Form FDA 483 citing this violation.

Defendants Were Warned About Their Violative Conduct

- 15. FDA repeatedly warned Defendants about their violative conduct. At the close of each of inspection since April 2003, FDA investigators issued to Bandith a Form FDA 483 identifying the observed violative conditions, and discussed each of the violations with him. Following the 2005 inspection and the subsequent seizure of adulterated articles of food, Defendants entered into a Consent Decree of condemnation and injunction in which they committed to maintain their facility in a sanitary condition, a commitment they promptly broke once oversight was relaxed.
- 16. In light of Defendants' lengthy history of non-compliance in the absence of strict oversight, Plaintiff is informed and believes that, unless restrained by this Court, Defendants will continue to violate 21 U.S.C. § 331(k) in the manner set fourth above.

WHEREFORE, Plaintiff respectfully requests that the Court:

- I. Permanently and perpetually restrain and enjoin Defendants and each and all of their officers, directors, agents, representatives, employees, successors and assigns, attorneys, and any and all persons in active concert or participation with any of them, under 21 U.S.C. § 332(a), from violating 21 U.S.C. § 331(k) by introducing or delivering, or causing to be introduced or delivered, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).
- II. Order that FDA be authorized pursuant to this injunction to inspect Defendants' place(s) of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any article of food to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

III. Order that Plaintiff is awarded costs and other such relief as the Court deems just and proper.

DATED this 5th day of October, 2010.

Of Counsel:

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